ORIGINAL

# In The United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**
**No. 08-0024V**
**Filed: December 08, 2014**
**(Not for Publication)**

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U.S. COURT OF FEDERAL CLAIMS

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HOWARD GREENBERG and DENISE GREENBERG, parents of JG, a minor,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

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Decision Dismissing "Table Encephalopathy" Claim; Statute of Limitations

*Howard and Denise Greenberg, Kihei, HI, pro se petitioners.*
*Lynn Ricciardella, U.S. Department of Justice, Washington, DC, for respondent.*

## DECISION

**HASTINGS, *Special Master***

This is an action in which Petitioners, Howard and Denise Greenberg, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of their son JG's autism spectrum disorder ("ASD"), which they contend was the result of a "Table Injury Encephalopathy" that occurred after an MMR vaccination on April 13, 2004. Because (1) their "Table Encephalopathy" claim was not timely filed, and (2) they have failed to show the existence of a Table Encephalopathy in JG, I hereby dismiss this petition.

## I

## THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006 ed.). Hereinafter, for case of citation, all § references will be to 42 U.S.C. (2006 ed.).

a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In this case, however, the Petitioners eventually chose to allege *only a Table Injury*. Thus, the standards for proving a "causation-in-fact" case are not relevant.

## II

## THE OMNIBUS AUTISM PROCEEDING ("OAP")

### *A. General*

This case is one of more than 5,600 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD") were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued by three special masters as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually to present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected a group of attorneys to present evidence in two different groups of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories on the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella (MMR) vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to

the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[2] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and then in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g.*, *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Cambell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584

[2] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

(Fed. Cl. Spec. Mstr. Hastings April 8, 2014) (autism not caused by MMR or Varivax vaccines). In addition, some autism claims have been rejected without trial, at times over the petitioners' objection, in light of the failure of the petitioners to file an expert report raising an issue requiring a hearing. *See, e.g.*, *Geppert v. HHS*, No. 00-286V, 2012 WL 2500852 (Fed. Cl. Spec. Mstr. Vowell Sept. 6, 2012); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g.*, *Fesanco v. HHS*, 2011 WL 1891701 (May 16, 2011) (Judge Braden).

In none of the post-test case rulings has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.

***B. Relevance of OAP to this case***

This case, however, is quite different from the cases cited in the OAP test cases and the other cases cited in the OAP discussion above. The issue here is *not* whether vaccines "caused-in-fact" JG's autism, but whether JG suffered a *Table Injury*, namely "encephalopathy," with the first symptoms of that encephalopathy occurring within the Table time period after vaccination. I ultimately conclude below JG did *not* suffer a "Table Encephalopathy. But it should be stressed that the evidence upon which I have relied in making my decisions is limited to the evidence set forth in *this* case. I include this section concerning the OAP *only* to show why this case, filed in 2008, was not processed in the usual manner of non-autism cases. Rather, because this case involved a child who had been diagnosed with autism, the processing of this case was *delayed*, along with the other 5,000 autism cases, to await the final outcome of the autism "test cases". Then, when the "test cases" were finalized in 2010, individual petitioners such as the Greenbergs were given a generous period of time to decide whether to abandon their claims or to develop a theory of their own case.

Only after Petitioners filed their Amended Petition on January 21, 2014, did the focus of this case *change* to a *Table Injury*, namely a Table Injury Encephalopathy allegedly associated with JG vaccinations of April 13, 2004.

Thus this case does *not* concern whether autism can be *caused* by the vaccinations that JG received, but *only* with whether JG suffered a Table Encephalopathy with the first symptoms of that encephalopathy within the Table time period after his MMR vaccination, and whether Petitioners' Table Encephalopathy claim was *timely filed.*

## III

## PROCEDURAL HISTORY OF THIS CASE

On January 14, 2008, Petitioners filed a "Short-Form Autism Petition for Vaccine Compensation" under the National Vaccine Injury Compensation Program, on behalf of their son, JG. (*See* Petition ("Pet") at 1.) The case was originally assigned to Special Master Gary Golkiewicz. (Notice of Assignment filed Jan. 14, 2008, ECF No. 2.)

Respondent's counsel filed a response on Feb. 25, 2008, opposing the petition.

Petitioners filed JG's medical records and other exhibits on March 20, 2008, and many other exhibits on many dates thereafter.[3]

By filing the "Short-Form Autism Petition", Petitioners in effect alleged that JG suffered from autism, and that his autism was caused by either or both (1) the MMR (measles, mumps, rubella) vaccine, and (2) vaccines containing "thimerosal", a mercury-based preservative contained in a number of childhood vaccines until about 1999 (but removed from most childhood vaccines soon after that year). *Autism General Order #1*, Exhibit A, Master Autism Peition for Vaccine Compensation, 2002 WL 31696785, at *8 (Fed. Cl. Spec. Mstr. July 3, 2002), available at http://www.uscfc.uscourts.gov/node/2718. They also were in effect, making their case part of the Omnibus Autism Proceeding (OAP). As a result, while the parties awaited the results of the "test cases" in the OAP, no formal proceedings were conducted to resolve the case for a considerable period of time. On June 3, 2008, the case was reassigned to Special Master John Edwards; on August 1, 2008, the case was reassigned to Special Master Christian Moran; and then on November 7, 2011, the case was reassigned to the docket of Special Master Denise Vowell, one of the three special masters handling the OAP and the autism "test cases."

As will be detailed below, in their many different documents filed in this case, Petitioners' theory of causation has varied. However, on January 9, 2013, Petitioners filed an expert report by Dr. Kevin M. Passer. (Pet. Ex. 23.) Dr. Passer stated that in his professional opinion, "the descriptions provided by [Petitioners] as to the observable reactions of their 12 month old are consistent with an acute attack of Encephalopathy or Encephalitis," and that JG's diagnosis ("PDD-NOS", a type of autism) is "a diagnosis which could apply to a child following a bout of Encephalopathy." (Pet. Ex. 23 at 3.) Although Dr. Passer did not specifically refer to the Vaccine Act, his report appears to allege that JG suffered a "Table Encephalopathy" as a result of his MMR vaccine at 12 months of age, on April 13, 2004.

On June 14, 2013, Petitioners expressed dissatisfaction with their attorney, Mr. Peck. Accordingly, Mr. Peck was relieved of the duties of counsel on June 21, 2013, and Petitioners proceeded *pro se* thereafter.

Because it was not clear to Chief Special Master Vowell on what theory or theories Petitioners wished to proceed, in an Order dated November 25, 2013, she ordered Petitioners to file an amended petition that clearly stated the causation theory or theories they were alleging.

Petitioners' Amended Petition, filed on January 21, 2014, alleges *only* a Table Encephalopathy claim. That filing points to vaccinations of April 13, 2014, as injuring JG, and cites the regulatory language applicable to a *Table Encephalopathy*. Therefore, I will address only that allegation of a Table Encephalopathy.[4]

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[3] Petitioners filed exhibits numbered 1 through 8 on March 20, 2008, and then a separate set of exhibits numbered 1 through 7 on September 15, 2008. Thus, when referring to any exhibits numbered 1 to 7, I will refer to either the 3-20-08 or 9-15-08 filing dates. After September of 2008, Petitioners filed exhibits numbered 16 through 142 on various dates.

[4] On May 16, 2014, this case was reassigned to the undersigned from Special Master Vowell.

## IV

## PETITIONERS' CAUSATION THEORY

As previously noted, Petitioners' theory of causation in this case has varied over time. As noted, by filing a Short-Form Autism petition, on January 14, 2008, Petitioners automatically elected to be part of the Omnibus Autism Proceeding ["OAP"]. Additionally, by filing a Short-Form Autism petition, Petitioners were deemed to be alleging that:

> [a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, [JG] developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza[e] Type B (HIB) vaccinations; or by some combination of the two.

*Autism General Order #1*, Exhibit A, Master Autism Petition for Vaccine Compensation, 2002 WL 31696785, at *8 (Fed. Cl. Spec. Mstr. July 3, 2002), *available at* http://www.uscfc.uscourts.gov/node/2718.

In their March 2008 filings, Petitioners stated that their claim "is not solely based on" JG's receipt of vaccines containing thimerosal, but rather that he was injured because of his inability to "digest" the vaccines. (Petitioners' Statement Regarding Respondent's Report, filed as Petitioners' Exhibit ["Pet. Ex."] 1 on March 20, 2008.) They noted that "a recent hair test [showed] mercury toxicity along with other toxic metals and deranged minerals," and that results of other testing led them to believe that JG's "autism is directly correlated to his inability to digest the contents of the vaccines." (Statement Regarding Onset, filed as Pet. Ex. 2.) Their filings also suggested that JG has symptoms associated with mitochondrial disorders and that they were working with doctors to confirm whether he has such a disorder. (*See* Pet. Exs. 1 and 2.)

Petitioners' February 2012 theory of causation statement (Pet. Ex. 17) noted that they "do not believe that any one vaccine caused [JG] to become autistic," but that "it was the vaccine schedule meaning all of the vaccines he received contributed to him becoming autistic."

However, on January 9, 2013, Petitioners seemed to change and narrow their causation theory in this case, when they filed an expert report by Dr. Kevin M. Passer. (Pet. Ex. 23.) Dr. Passer stated that in his professional opinion, "the descriptions provided by [Petitioners] as to the observable reactions of their 12 month old boy are consistent with an acute attack of Encephalopathy or Encephalitis," and that JG's diagnosis (PDD-NOS, a form of autism) is "a diagnosis which could apply to a child following a bout of Encephalopathy." (Pet. Ex. 23 at 3.) Although Dr. Passer did not specifically refer to the Vaccine Act, his report appears to be alleging that JG suffered a "Table Encephalopathy" as a result of his MMR vaccine, at 12 months of age, on April 13, 2004.

Because it was not clear to Chief Special Master Vowell on what theory or theories Petitioners wished to proceed, in an Order dated November 25, 2013, she ordered Petitioners to file an amended petition that clearly stated the causation theory or theories they were alleging.

Petitioners' Amended Petition, filed on January 21, 2014, alleges *only* a Table Encephalopathy claim. That filing points to vaccinations of April 13, 2004, as injuring JG, and cites the regulatory language applicable to a *Table Encephalopathy*. Therefore, I will address only that allegation of a Table Encephalopathy.[5]

## V

## SUMMARY OF FACTS AND EVIDENCE RELEVANT TO PETITIONERS' TABLE ENCEPHALOPATHY CLAIM

### *A. Medical records*

JG was born on April 10, 2003. JG had his one-year well-child visit on April 13, 2004, three days after his first birthday. (Pet. Ex. 3, filed 3-20-08, p. 11.) He passed all of the applicable developmental milestones, and was assessed as a well child. He received the allegedly causal vaccine at this visit: MMR as well as a Varivax vaccine. (*Id.*, pp. 1-2, 11.)

The pediatric records indicate that between JG's one-year and 18-month well-child visits, Petitioners made three phone calls to his pediatrician. On April 23, 2004, Mrs. Greenberg called and conveyed that JG was very fussy with swollen gums due to his molars coming in. He did not have a fever, and Petitioners were advised to give him Advil. (*Id.*, p. 15.) The next call occurred on May 28, 2004, and was initiated by Mr. Greenberg. He reported that JG was having a reaction due to an overload of vitamin C. JG had non-itchy, little bumps on his leg, stomach, and arms. Petitioners were advised to monitor his condition and decrease his vitamin C intake. Additionally, if his skin looked dry, Petitioners were to apply moisturizer. (*Id.*) The final call was placed on June 4, 2004. After having a small amount of peanuts, JG began wheezing and his mother was concerned it was an allergic reaction. (*Id.*, p. 9.) Petitioners were instructed to obtain albuterol syrup and told to have JG avoid all nuts, including peanut butter. (*Id.*)

On July 13, 2004, at his fifteen-month well-child visit, JG was described as a well-child with a history of bronchospasms. He received his fourth Hib vaccine at this visit. The history indicates there were *no reactions* to his prior shots, and that he had been experiencing wheezing for six weeks, which corresponds to the possible allergic reaction to peanuts. JG was reported to be walking without support, drinking from a cup, self-feeding, stacking blocks, and indicating wants without crying. (*Id.*, p. 11.)

[5] In the version of the Vaccine Injury Table applicable to this case, there is a Table Injury of "Encephalopathy" for the *MMR* vaccine, but no Table Injury of any kind listed for the *varicella* vaccine, which JG received on April 13, 2004, along with his MMR vaccination. Thus, obviously, Petitioners' only potential Table Injury claim is a Table Encephalopathy related to the *MMR* vaccine. 42 C.F.R. § 100.3(a).

JG's eighteen-month well-child visit occurred on October 13, 2004. The history reported that he was doing well and, again, that he had experienced *no reaction* to his prior shots. He received his fourth DTaP and pneumococcal vaccines at this visit. Petitioners refused consent for the influenza vaccination. JG was assessed as a well-child, who walked well, kicked and threw balls, and used 3 words other than mama and dada. (*Id.*, p. 10.)

At his two-year well-child visit on April 12, 2005, JG was assessed as a well child, but concerns were raised about his development. It was noted that he only sometimes used two-word phrases, had tantrums, and exhibited screeching. Petitioners were instructed to schedule a re-evaluation of his speech and behavior in six months if no progress had been made. (*Id.*, p. 10.)

By the time of a developmental evaluation on January 5, 2006, JG's development was clearly significantly abnormal. He was diagnosed with "Pervasive Developmental Disorder – Not Otherwise Specified" (PDD-NOS), a form of autism. (Pet. Ex. 5, p. 5, filed on March 20, 2008.)

***B. Parental statements and affidavits***

***1. Statement of March 13, 2008, regarding onset***

In their statement regarding onset, Petitioners stated that they "first noted a delay in [JG's] development at his 2 year immunization check up." (Pet. Ex. 2 at 1, filed March 20, 2008.) The pediatrician assured them at that time that JG "still had good eye contact, was by no means autistic, but was just developing verbally slowly." (*Id.*) Petitioners thought that the regression or stalling in his development might be a psychological reaction to the birth of his younger sister, who at the time was 4 months old, but they nevertheless sought assistance from an early intervention program. (*Id.*) Petitioners did not allege any relevant symptoms in JG any earlier than at the time of his two-year check-up.

Ultimately, the symptoms first noted by Petitioners at around the time of JG's two-year visit proved to be early symptoms of autism--he was later diagnosed with PDD-NOS, a form of autism. (Ex. 5, p. 5, filed on March 20, 2008.)

***2. Letter of Dr. Frank Baum, dated July 20, 2008***

On September 15, 2008, Petitioners submitted exhibits numbered 1 through 7. In Ex. 2, Doctor Baum, JG's pediatrician, wrote a "to whom it may concern" letter dated July 20, 2008.

Doctor Baum stated that no "red flags" were raised during the modified Denver Developmental evaluation performed at JG's 18-month well-child visit. (Pet. Ex. 2, filed 9-15-08, p. 1.) In contrast, wrote Dr. Baum, at JG's two-year well-child visit, Dr. Baum found disturbing symptoms, including JG's failure to play with other children and JG's tendency to screech and make lots of sounds. (*Id.*) Doctor Baum noted that he had suggested a re-evaluation of JG in six months, at 2.5 years of age, if no further progress had been made in his speech and

behavior skills. (*Id.*) Additionally, Dr. Baum noted that he had "*no notations in JG's medical record of any unusual vaccine reactions.*" (*Id.* at 2, emphasis added.)

***3. Affidavit of Petitioners, dated September 13, 2008***

Another of the seven documents filed on September 15, 2008, was Ex. 1, a joint affidavit of the Petitioners executed on September 3, 2008. In their affidavit, Petitioners indicated that they first experienced concerns about JG's lack of speech development around the time of his two-year well-child visit. (Ex. 1 at 1.) They stated that a report prepared by Dr. Galler-Rim, following an evaluation of JG when he was 2 years and 9 months of age, incorrectly placed onset of his developmental delay at 18 months. Petitioners stressed that JG was "still progressing normally" at 18 months. (*Id.*)

***4. Petitioners' Interrogatory Responses executed on January 15, 2009***

On December 9, 2008, Respondent's counsel mailed Petitioners a list of eight questions. Petitioners' responses to the questions were filed by Respondent on February 5, 2009. (See Ex. A and Ex. B, filed Feb. 5, 2009.)

Petitioners indicated that they first thought their son might be autistic after seeing an episode of the "Super Nanny" television show that featured an autistic child. The child in the episode had behaviors similar to those they were observing in JG. Because they saw the episode about a week or ten days before his already-scheduled two-year well-child visit, they did not schedule a special appointment with their pediatrician to discuss their concerns. (Interrogatory No. 2.)

Petitioners reported that JG was able to easily repeat words at his 18-month check up, and believed that his inability to do so was a concern at his 2-year check up. (Interrogatory No. 4.)

***C. Expert reports***

***1. Dr. Kevin Passer***

As previously noted, Petitioners filed the expert report of Dr. Kevin Passer on January 9, 2013. (Pet. Ex. 23.) Dr. Passer is a board-certified child and adolescent psychiatrist based in Hattiesburg, MS. He completed his fellowship training at Johns Hopkins. (*Id.* at 1) His expert report addressed four specific questions: (1) "How is PDD-NOS diagnosed in a 2 year old patient?" (2) "What are the ranges of OBSERVABLE symptoms for an acute attack of Encephalopathy or encephalitis in a 1 year old child?" (3) "Can long-term injury that results from an acute attack of Encephalopathy or encephalitis result in observable symptoms that could be diagnosed as PDD-NOS?" and (4) "Does the parent statement of Denise Greenberg, dated December 12, 2012, fit within descriptive parameters for an attack of acute Encephalopathy or encephalitis, by a parent without medical knowledge?" (*Id.* at 1-3.)

After providing short answers to the four questions that he posed, Dr. Passer concluded that in his "professional opinion, the descriptions provided by the parent as to the observable

reactions of their 12 month old boy are consistent with an acute attack of Encephalopathy or Encephalitis." (Pet. Ex. 23 at 3.) In reaching his conclusion, Dr. Passer stated, he relied upon a statement of Ms. Greenberg dated December 12, 2012, in which she wrote that Petitioners "first noticed that JG was sick when he had a fever and seemed very sensitive to his surroundings like to light and sound. He just seemed weak and out of it and very irritable." (*Id.* A copy of the December 12, 2012, statement was filed in this case on January 27, 2014, as Petitioners' Exhibit 140.) That statement, by Ms. Greenberg, however, does *not* associate her observations with a particular date or timeframe. It does note that "JG remained in this state of delirium for over a day." (Ex. 140 at 1.)

***2. Dr. John Green, III***

Dr. Green is a physician who specializes in Allergy & Environmental Medicine and Childhood Disorders. His clinic, EverGreen Center PC, is located in Oregon City, OR. (Pet. Ex. 141, filed on January 17, 2014, at 1.) In April 2010, Dr. Green wrote a "disability letter" in which he stated that "[JG] is disabled by inability to communicate effectively, by inordinate, intractable behaviors, and by multiple complex metabolic problems resulting in metabolic encephalopathy." (*Id.*) In that letter, however, Dr. Green did *not* state any opinion as to the *cause* of JG's "metabolic encephalopathy," nor did he state that JG's encephalopathy followed his MMR vaccine. Thus, this expert report provides no support to Petitioners' Table Injury claim in this case.

## VI

## PETITIONERS' "TABLE INJURY" CLAIM IS CLEARLY TIME-BARRED

As noted above, under the Vaccine Act, the petitioner bears the burden of proving a vaccine-caused injury.[6] There are two ways causation may be demonstrated. First, a petitioner may establish a "Table Injury."[7] Alternatively, a petitioner may prove that a vaccine listed on the Table actually caused or significantly aggravated an injury (an "off-Table" injury). In this case, Petitioners allege only that JG suffered a "Table Encephalopathy" following his MMR vaccination on April 13, 2004. (See Amended Petition filed on January 27, 2014; Pet. Ex. 23.)

To succeed with their Table Encephalopathy claim, petitioners must demonstrate (1) that their petition was timely filed, and (2) that JG's symptoms satisfy the statutory definition for a Table Encephalopathy. Petitioners are able to do neither, as I will demonstrate in this Section VI of this Decision, plus the following Section VII.

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[6] Petitioners have the burden of demonstrating the facts necessary to show their entitlement to an award by a "preponderance of the evidence." § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

[7] *See* § 11(c)(1)(C); 42 C.F.R. § 100.3 (2010).

### *A. Legal standard: Statute of Limitations*

The Vaccine Act's statute of limitations provides that, in the case of:

> a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . .

§ 16(a)(2).

The date of occurrence "is a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Cloer v. HHS,* 654 F.3d 1322, 1339 (Fed. Cir. 2011) (en banc), *cert. denied, Cloer v. Sibelius*, 132 S. Ct. 1908 (2012). Additionally, the date "does not depend on the knowledge of a petitioner as to the cause of an injury." (*Id.* at 1338.) When drafting the Vaccine Act, Congress rejected a "discovery rule"-based statute of limitations, in favor of one that does *not* consider knowledge, and runs solely from the date of an *event*, the first symptom or manifestation of onset. (*Id.)*

In *Cloer*, the Federal Circuit acknowledged that "equitable tolling"[8] applies in Vaccine Act cases, but under very limited circumstances, such as when a petitioner was the victim of fraud or duress, or when a procedurally deficient pleading was timely filed. *Cloer*, 654 F.3d at 1344-45. It squarely rejected the applicability of equitable tolling "due to unawareness of a causal link between an injury and administration of a vaccine." *Id.* at 1345.

### *B. Application of statute of limitations to Petitioners' Table Encephalopathy claim*

Combining the Vaccine Act's 36-month statute of limitations, with its requirement that the first symptoms of an MMR-caused "Table Encephalopathy" must occur within 15 days of the vaccination (42 C.F.R. § 100.3(a)), to be considered timely-filed the petition in this case must have been filed by April 28, 2007--*i.e.*, 3 years and 15 days after the MMR in question. Because the petition was not filed until January 14, 2008, it was untimely filed.

Petitioners argue that the late filing of their petition should be excused because of misrepresentations and fraud committed by the United States Government. (Petitioners' Response to Respondent's Motion to Dismiss, filed June 14, 2013, at 2; *see also* Amended Petition, filed Jan. 27, 2014, at 3.)

In reviewing their allegation, Special Master Vowell noted that the documents which Petitioners filed concerning the alleged fraud (Exs. 25-139) were generally focused on studies exploring *thimerosal*, a mercury-based preservative contained in *some* vaccines, its possible role in autism, and the government's alleged misconduct in certain published articles and the study

[8] The doctrine of equitable tolling is a legal principle that acts to overcome a statute of limitations problem in certain situations. If a case is untimely filed and the doctrine of equitable tolling applies, then the case will be permitted to continue.

results concerning thimerosal that such articles contained. (Order, issued Nov. 25, 2013, at 5.) She conceded that a few of the documents refer to MMR and autism, but that on their own such articles could not support an allegation of fraud pertinent to a Table Encephalopathy claim. (*Id.*) Petitioners were cautioned that if they intended to pursue a Table claim and assert that it should be considered timely-filed because of fraud, they must establish that the alleged fraud is *relevant to the claim*. Additionally, because their filed evidence focused primarily on research involving thimerosal-containing vaccines, Special Master Vowell advised that, if Petitioners intended to rely on those documents, they must establish that the MMR vaccine that JG received contained thimerosal. (*Id.*)

In their Amended Petition, filed on January 21, 2014, Petitioners replied that "their son's HIB, DTaP, IPV, and Hep B contained thimerosal." (Amd. Pet. at 3.) Petitioners did *not* argue, much less establish, that the *MMR* vaccination JG received contained thimerosal.[9] Nor did Petitioners link the alleged fraud to their own Table Encephalopathy claim. Asserting a "Table Encephalopathy" claim is different than a causation-in-fact claim regarding vaccines and autism, as Chief Special Master Vowell explained to Petitioners during the November 2013 status conference and in her subsequent order. (Order of November 25, 2013.) Establishing fraud regarding *thimerosal* and autism, as Petitioners assert occurred via Paul Thorsen and a 2002 Danish study (see Amd. Pet. at 2-3),[10] does *not* warrant an application of equitable tolling to petitioners' *MMR Table Encephalopathy* claim.

As discussed in Section VII of this Decision below, the *facts* of this case do *not* in any event meet the Vaccine Act's standard for demonstrating a Table Encephalopathy. Therefore, I technically need not determine whether Petitioners have established that fraud occurred or if it is

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[9] In fact, I am aware, from the autism "test cases" cited above, that the MMR vaccine does *not* contain thimerosal. *E.g.*, *Dwyer v. HHS*, No. 03-1202V, 1010 WL 892250, at *171, fn. 635.

[10] In their many exhibits filed in this case, Petitioners allege fraud by a Danish vaccine researcher named Thorsen, and by others, in regard to the controversy concerning whether *thimerosal-containing vaccines* ("TCVs") can cause autism. As noted above, this alleged fraud has proven to be *irrelevant* to this case, in which Petitioners ultimately relied only upon a theory of a "Table Encephalopathy" after an *MMR* vaccination of April 13, 2004, since MMR vaccines do *not* contain thimerosal. Nevertheless, I do not wish to leave the impression in this Decision that Petitioners have *proven* fraud concerning the theory that TCVs can cause autism. To the contrary, I note that after weeks of trial in which some of the world's top autism experts testified, in the "test case" decisions, three different special masters of this court, in three separate rulings combining to stretch hundreds of pages in length, each *strongly rejected* the idea of any causal connection between TCVs and autism. See *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. March 12, 2010) (my own ruling); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. March 12, 2010) (ruling by Special Master Campbell-Smith, now Chief Judge of this Court); and *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Sec. Mstr. March 12, 2010) (ruling by Special Master Vowell, now Chief Special Master). Each of the three opinions rejected the alleged causal connection for *many different reasons*, in *addition* to the negative epidemiologic studies as to which the Petitioners in this case allege fraud. And even in the single area of *epidemiologic studies*, each of the three special masters relied upon *many* epidemiologic studies by different researchers from different countries. (*E.g.*, *King*, 2010 WL 892296, at *63-*67.) Thus, even if one or even a few of those epidemiologic studies were discredited--and I have made *no ruling* concerning that irrelevant assertion in this case--such discrediting clearly would *not* discredit the *overall overwhelming weight* of the evidence cited in three test cases cited above, which found no merit to the alleged TCV-autism connection, based not only upon *many* epidemiologic studies, but also upon *many other* ways in which the alleged causal connection was shown to be scientifically highly unlikely.

the type of fraud contemplated by the Federal Circuit in *Cloer* as invoking equitable tolling in Vaccine Act cases. Even if I were to accept petitioners' arguments and apply equitable tolling (and thus not dismiss their petition for untimely filing), their Table claim would still have to be dismissed for failing to meet the Table's injury requirements.

However, it is quite clear that this petition, which Petitioners, in their Amended Petition, have now narrowed to a Table Encephalopathy claim with respect to the MMR vaccination of April 13, 2004, was filed far out of time with respect to that April 2004 *Table Encephalopathy* claim. Nor, even *assuming* that the Danish study by Thorsen was a fraudulent study, would that extend the statute of limitations for Petitioners' claim, since that alleged fraud concerns the issue of *thimerosal-containing vaccines*, and has nothing to do with the issue of whether an MMR vaccine, which does *not* contain thimerosal, could cause autism.[11]

## VII

## PETITIONERS CLEARLY HAVE *FAILED* TO DEMONSTRATE THAT JG SUFFERED A "TABLE ENCEPHALOPATHY"

### A. *Introduction*

As noted above, I could dismiss this claim *either* because it was not timely filed, *or* because Petitioners have failed to demonstrate that JG suffered a Table Encephalopathy. Thus, having found in Section VI of this Decision that their petition clearly was *not* timely filed with respect to their Table Encephalopathy claim, I could end my analysis at that point. However, in the interest of completeness, I will now analyze the *merits* of the Table Encephalopathy claim. I find that JG did *not* suffer a Table Encephalopathy, for the reasons set forth below.

### *B. Legal standard: Table Encephalopathy*

For petitions, such as this one, filed after the modifications to the Vaccine Injury Table that went into effect on March 24, 1997, "encephalopathy" exists as a Table Injury for MMR vaccinations. I will set forth the relevant Table Injury definition below.[12]

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[11] Since this case was transferred to me, on May 16, 2014, I have examined the many documents filed by Petitioners. I agree completely with the analysis of Special Master Vowell, in her Order issued on November 25, 2013, concerning Petitioners' Exs. 25-139 and Petitioners' allegations concerning "fraud." As Special Master Vowell concluded, the allegations in those documents concerning fraud in the medical community's analysis of *thimerosal-containing vaccines* is *irrelevant* to the *only* claim that Petitioners have raised in their Amended Petition, that JG's *MMR* vaccination caused a Table Encephalopathy in April of 1994.

Further, I have examined the other documents filed by Petitioners in this case, including, but not limited to, Exhibits 140 and 141 filed on January 27, 2014, with their Amended Petition, and the additional exhibits filed on September 12, 2014, with duplicative exhibit numbers, Exs. 140-42. Again, I find no evidence of fraud by anyone relating to Petitioners' "Table Encephalopathy" claim.

[12] The statute itself contains a version of the Vaccine Injury Table that applied to vaccinations administered prior to the enactment of the Program and for several years after that enactment. See § 300aa-14(a). However, the Vaccine Injury Table was administratively modified with respect to Program petitions, such as this one, that were filed after March 24, 1997. See 62 Fed. Reg. 7685, 7688 (1997); *O'Connell v. Shalala*, 79 F.3d 170 (1st Cir. 1996). That

**§ 100.3 Vaccine injury table.**

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, * * * the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the program:

**VACCINE INJURY TABLE**

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestion of onset or of significant aggravation after vaccine administration |
|---|---|---|
| * | * | * |
| Measles, mumps, rubella, or any of its components (*e.g.*, MMR, MR, M, R) | A. Anaphylaxis or anaphylactic shock | 4 hours |
| | B. Encephalopathy (or encephalitis) | 5-15 days (not less than 5 days and not more than 15 days). |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed | Not applicable |
| * | * | * |

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

* * *

(2) *Encephalopathy.* For purposes of paragraph (a) of this section a vaccine recipient shall be considered to have suffered an encephalopathy only if such

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Table modification, along with an earlier administrative modification of the Table in 1995 (see 60 Fed. Reg. 7678 (1995)), significantly altered the "Table Injury" categories with respect to the MMR vaccination from the version of the Table contained in the statute. The portion of the new Table applicable to this case, listing "encephalopathy" as a Table Injury for the MMR vaccination, appears at 42 C.F.R. § 100.3(a)(III)(B) (10-1-97 edition of C.F.R.--all C.F.R. references in this Decision will be to the 10-1-97 edition of the C.F.R.).

recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

* * *

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

* * *

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination.

42 C.F.R. § 100.3 (10-1-97 edition of C.F.R.).

Thus, to establish their Table Encephalopathy claim, under the regulatory language set forth above, Petitioners must demonstrate that JG manifested an injury encompassed in the definition of an "acute encephalopathy" within 5 to 15 days of his MMR vaccination, and that a "chronic encephalopathy" was then present for more than 6 months after the acute encephalopathy. 42 C.F.R. § 100.3(b)(2).[13]

For a child younger than 18 months, presenting without an associated seizure event, an acute encephalopathy is indicated "by a significantly decreased level of consciousness . . . lasting for at least 24 hours." § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is demonstrated by the presence of one of three clinical signs for a period of at least 24 hours: "(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things)." § 100.3(b)(2)(i)(D). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are not, alone, or in combination, a demonstration of an acute encephalopathy. § 100.3(b)(2)(E).
An acute encephalopathy is an event "that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i).[14]

A chronic encephalopathy is defined in the QAI as "a change in mental or neurologic status, first manifested during the applicable time period, [that] persists for a period of at least 6 months from the date of vaccination." § 100.3(b)(2)(ii).

The clinical signs and symptoms of an acute encephalopathy were incorporated into the QAI to "clearly distinguish infants and children with brain dysfunction from those with transient 'lethargy.'" Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687. As noted in *Waddell*, by then-Chief Special Master Campbell-Smith,[15] the QAI definition of "significantly decreased level of consciousness" implies "a state of diminished alertness that is much more than mere sleepiness or inattentiveness . . . . [It] requires markedly impaired--or strikingly absent--responsiveness to environmental or external stimuli, for a sustained period of at least twenty-four hours." *Waddell v. HHS*, No. 10-316V, 2012 WL 4829291, at *7 (Fed. Cl. Spec. Mstr. Sept. 19, 2012).

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[13] The QAI section of the Vaccine Injury Table, 42 C.F.R. § 100.3(b), contains *definitions* for the terms, such as "encephalopathy," used in the Table. *See Althen v. HHS*, 58 Fed. Cl. 270, 280 (2005), *aff'd*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the Table).

[14] When revising the QAI definition, it was noted that the hospitalization requirement was not intended "as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event." Revision of the Vaccine Injury Table, 60 Fed. Reg. 7685, 7687 (Fed. 20, 1997) (preamble to final rule).

[15] On September 19, 2013, Chief Special Master Campbell-Smith was appointed Judge of the U.S. Court of Federal Claims. On October 21, 2013, Judge Campbell-Smith was designated as the Chief Judge of the U.S. Court of Federal Claims.

The revised QAI definition aimed to differentiate between the "diminished alertness and motor activity [] which characterize [a] lethargic infant or child" and the "more serious impairment of consciousness that is the hallmark of encephalopathy (i.e., obtundation, stupor and coma)." Revision of the Vaccine Injury Table, 60 Fed. Reg. at 7687; *see also Romano v. HHS*, No. 90-1423, 1993 WL 472879, at *6 (Fed. Cl. Spec. Mstr. Nov. 1, 1993). Therefore, dramatic or severe symptoms must be present to meet the Table Encephalopathy definition.[16]

### *C. Analysis of Petitioners' Table Encephalopathy claim*

Petitioners have clearly failed to show that JG suffered an "acute encephalopathy" as defined by the regulatory language set forth above, and have *also* failed to show that he suffered a "chronic encephalopathy" thereafter. Accordingly, they have clearly failed to show that JG experienced a "Table Encephalopathy."

#### *1. Acute Encephalopathy*

The evidence in the record clearly contradicts the Petitioners' claim that JG suffered an "acute encephalopathy," with onset of symptoms 5 to 15 days after his MMR vaccination of April 13, 2004. As noted, Dr. Passer based his diagnosis of an acute encephalopathy, after the MMR vaccination of April 13, 2004, upon a statement of Petitioner Denise Greenberg dated December 12, 2012, which stated that "we first noticed that Joshua was sick when he had a fever and seemed very sensitive to his surroundings like to light and sound. He just seemed weak and out of it and very irritable." (Pet. Ex. 23, p. 3.) That statement of Ms. Greenberg was later filed as an attachment to Petitioners' Amended Petition on January 27, 2014. But that statement, does *not* say that such fever and other symptoms occurred at any particular time, much less soon after the MMR vaccination of April 13, 2004. (Amended Petition, Jan. 27, 2014, p. 5.) Second, even if those symptoms *did* occur 5 to 15 days after the MMR vaccination in question, in fact the above description by Ms. Greenberg clearly does *not* match the regulatory definition of an acute encephalopathy, set forth above, which requires a "significantly decreased level of consciousness lasting for at least 24 hours," with "decreased or absent response to environment," "decreased or absent eye contact", or "inconsistent or absent response to external stimuli." (42 C.F.R. § 100.3(b)(2).) To the contrary, to the extent that Ms. Greenberg describes JG as "very sensitive to his surroundings," and "very irritable," her description is in fact the *exact opposite* of the Table Encephalopathy definition quoted above--*i.e.* "decreased or absent response to environment."

[16] *See, e.g., Jay v. HHS*, 998 F.2d 979, 981, 984 (Fed. Cir. 1993) (noting the Special Master's comment that "[w]ith an encephalopathy we typically seen at least one dramatic aspect. This aspect is what separates the events from the normal range of DTP reactions"; and concluding that the "dramatic aspect" in the case was the child's death); *Gamache v. HHS*, 27 Fed. Cl. 639, 642 (1993) (upholding a dismissal decision in which the special master had concluded that "screaming and crying in and of themselves are not conclusive evidence of encephalopathy. [The vacinee's] high-pitched and unusual screaming and inconsolable crying are explainable as a local, systemic reaction to the DPT vaccine rather than as indicia of encephalopathy.") *Watt v. HHS*, No. 99-25V, 2001 WL 166636, at *8 (Fed. Cl. Spec. Mstr. Jan. 26, 2001) (citing expert testimony that the symptoms relied upon to establish a Table Encephalopathy "cannot merely be crying, it cannot--inconsolable crying; it cannot merely be crankiness; it cannot merely be a number of things.").

Moreover, JG's *medical records* at the time of the alleged "acute encephalopathy" show no indication at all of an acute encephalopathy. The records of the visit on April 13, 2004, show no reaction to the vaccination. (Ex. 3, p. 11, filed March 20, 2008.) The pediatric records do *not* show any return visit by JG to his pediatrician in the following weeks. Over the three-month period after the April 2004 MMR, the records show only three phone calls by his parents.

On April 23, 2004, Mrs. Greenberg called and conveyed that JG was very fussy with swollen gums due to his molars coming in. He did not have a fever, and Petitioners were advised to give him Advil. (*Id.*, p. 15.) The next call occurred on May 28, 2004, and was initiated by Mr. Greenberg. He reported that JG was having a reaction due to an overload of vitamin C. JG had non-itchy, little bumps on his leg, stomach, and arms. Petitioners were advised to monitor his condition and decrease his vitamin C intake. (*Id.*) The final call was placed on June 4, 2004. After having a small amount of peanuts, JG began wheezing and his mother was concerned it was an allergic reaction. (*Id.*, p. 9.) Petitioners were instructed to obtain albuterol syrup and told to have JG avoid all nuts, including peanut butter. (*Id.*)

JG's next visit to the pediatrician was on July 13, 2004, for his fifteen-month well-child visit. (*Id.*, p. 11.) At that visit, JG was described as a well-child with a history of bronchospasms. The history indicates there were *no reactions to his prior shots*, and that he had been experiencing wheezing for six weeks, which corresponds to the possible allergic reaction to peanuts. JG was reported to be walking without support, drinking from a cup, self-feeding, stacking blocks, and indicating wants without crying. (*Id.*)

JG's next pediatrician visit, his eighteen-month well-child visit, occurred on October 13, 2004. (*Id.*, p. 10.) The history reported that he was doing well and, again, *had no reaction to his prior shots*. JG was assessed as a well-child, who walked well, kicked and threw balls, and used 3 words other than mama and dada. (*Id.*)

JG's next pediatrician visit was at his two-year well-child visit on April 12, 2005. (*Id.*, p. 10.) It was only at that two-year visit that concerns were raised about his development. (*Id.*)

In sum, JG's medical records for the full year following his MMR vaccination offer *no evidence whatsoever that* he suffered a Table Encephalopathy after that vaccination. To the contrary, the records from both his 15-month and 18-month checks state plainly that he had *no reaction to his prior shots*.

In addition, even the first statement about JG made by *Petitioners themselves* in this case makes *no mention whatsoever* of an encephalopathic reaction or *any* reaction to the MMR vaccination of April 2004. On March 20, 2008, Petitioners filed their Ex. 2, a Statement Regarding Onset by Petitioner Denise Greenberg. (Ex. 2.) That statement reports no problems with JG until shortly before his *two-year check-up*. (*Id.*)

In sum, when I evaluate the record of this case as a whole, it becomes *completely clear* that JG did *not* suffer an "acute encephalopathy."

***2. Chronic Encephalopathy***

Petitioners assert that JG suffered an acute encephalopathy after his April 2004 MMR vaccine. Therefore, a *chronic encephalopathy* must have persisted in JG from then until at least October 2004, to meet the statutory definition for a Table Encephalopathy.

The evidence, however, clearly demonstrates that JG did *not* suffer a *chronic encephalopathy* that lasted more than six months after his alleged acute encephalopathy. The medical records from JG's 15-month well child visit (July 13, 2004) and his 18-month well-child visit (October 13, 2004) indicate that he was a well child, who was developing normally. (Ex. 3, pp. 10-11.) Concerns about his development were not raised with his pediatrician until his two-year well-child visit in April 2005. (Pet. Ex. 3, filed 3-20-08, p. 10.) Additionally, Petitioners' written statements, affidavit, and interrogatory responses, as well as Dr. Baum's affidavit, all convey that JG was *developing normally* up until sometime around his second birthday, or at least until sometime after he was 18 months old.[17] (See evidence discussed at pp. 8-9, above.)

In sum, because JG's medical records indicate no neurologic abnormalities in the six-month period after the vaccination in question, as demonstrated by his routine 15-month and 18-month well-child visits, he cannot be considered to have suffered a "chronic encephalopathy" following the alleged acute encephalopathy triggered by his MMR vaccination. Thus, petitioners cannot establish that JG meets the Vaccine Act's requirements for a Table Encephalopathy injury claim.

## VIII
## CONCLUSION

Petitioners' "Table Encephalopathy" claim is hereby dismissed, because (1) that claim was not timely filed, and (2) Petitioners have failed to introduce evidence that would establish that a "Table Encephalopathy" occurred.

Further, Chief Special Master Vowell ordered Petitioners to include *in their* amended petition, *all* of the causation theories on which they wished to proceed. (Order, issued Nov. 25, 2013, at 4-5.) Because Petitioners, in response, filed an Amended Petition that included *only* an allegation of a Table Encephalopathy, and they have *failed* to establish either that a Table Encephalopathy occurred or that their Table Encephalopathy claim was timely filed, I must dismiss this claim.[18]

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[17] Petitioners' expert reports do not address whether JG exhibited behaviors consistent with a chronic encephalopathy. Doctor Passer's report only addresses the presence of an *acute* encephalopathy, while Dr. Green's report opines that JG suffered from a metabolic encephalopathy, and does not identify such encephalopathy as caused by or occurring soon after any particular vaccine. Further, as to Dr. Green's report, which opined that JG suffered a "metabolic encephalopathy," the QAI specifies that "an encephalopathy shall not be considered to be a condition set forth in the Table if . . . the encephalopathy was caused by an infection, a toxin, a *metabolic* disturbance . . . ." (§100.3(b)(2)(iii), emphasis added.)

[18] Because, as demonstrated in Section VI of this Decision, it is clear that Petitioners' Table Encephalopathy claim is *time-barred, and*, as demonstrated in Section VII of this Decision, it is clear that Petitioners' Table Encephalopathy claim is *without merit*, it is appropriate for me to decide this case without an evidentiary hearing. See Vaccine Rule 8(d) (a special master has discretion to decide a case without an evidentiary hearing when appropriate under the circumstances).

Some additional comments, however, are also in order.

The record of this case demonstrates plainly that JG and his family have been through a tragic ordeal. I have noted the records describing JG's medical history, and the efforts of his family in caring for him. The dedication of JG's family to his welfare is readily apparent to me.

I have no doubt that JG's parents are sincere in their belief that vaccines played a role in causing JG's *autism*. JG's parents obviously have read the writings of physicians who profess to believe in a causal connection between vaccines and autism. After studying the evidence in this case, and many other cases (see "test cases" mentioned at p. 3 below), I have seen *no* persuasive evidence whatsoever of such a causal connection. Nevertheless, I can understand why JG's parents found such opinions to be believable under the circumstances. I conclude that the Petitioners filed this Program claim in good faith.

Thus, I feel deep sympathy for the Greenberg family. Further, I find it unfortunate that my ruling in this case means that the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to the families of *all* autistic children, *regardless* of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on JG's behalf.[19]

In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.

**IT IS SO ORDERED.**

**George L. Hastings, Jr.**
Special Master

[19] I also note that the Petitioners filed this case nearly seven years ago. Yet in all that time Petitioners have failed to file a viable expert report. They have been given a fair chance to prove that JG's autism was connected to a vaccination, but have failed to do so.